

PATENT COOPERATION TREATY

PCT/US98/22

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 09 July 1999 (09.07.99)	Applicant's or agent's file reference 23739-PCT
International application No. PCT/US98/22372	
International filing date (day/month/year) 23 October 1998 (23.10.98)	Priority date (day/month/year) 23 October 1997 (23.10.97)
Applicant HINZE, Gilbert, Theo	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
21 May 1999 (21.05.99)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer R. Forax
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

2724161



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 33/00, 33/04, 33/14, 33/20, 33/40, A01N 59/00, 59/02, 59/08, A61L 2/00, 2/02, 2/16, 2/18, 9/14, C01B 7/03, 11/00, 13/00, 15/00, C25B 1/00, 1/02, 1/04, 1/14, 1/24, 1/26, 1/28, 1/30, 1/34	A1	(11) International Publication Number: WO 99/20287 (43) International Publication Date: 29 April 1999 (29.04.99)
(21) International Application Number: PCT/US98/22372 (22) International Filing Date: 23 October 1998 (23.10.98) (30) Priority Data: 97/9486 23 October 1997 (23.10.97) ZA (71) Applicant (for all designated States except US): MOISEL, Ekkehard, Walter [ZA/ZA]; 22 Forge Road, Spartan 1619 (ZA). (71) Applicant (for BB only): DAVIS, Joanne, T. [US/US]; 714A 15th Street, Arlington, VA 22202 (US). (71)(72) Applicant and Inventor: HINZE, Gilbert, Theo [ZA/ZA]; 119 Ostrich Road, Bromhof, Randburg 2194 (ZA). (74) Agent: NATH, Gary, M.; Nath & Associates, 6th floor, 1030 15th Street, N.W., Washington, DC 20005 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: THE USE OF AN AQUEOUS SOLUTION IN THE PREPARATION OF A MEDICAMENT FOR USE IN THE TREATMENT OF LIVE ANIMALS (57) Abstract This invention relates to a composition for use in the treatment of pathogenic microorganisms in a live animal, the composition comprising an electro-chemically activated, anion-containing aqueous solution.		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/22372

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : Please See Extra Sheet.

US CL : Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/600, 613, 615, 616, 661-665, 677-681; 422/22, 23, 29, 37; 252/186.21, 186.22, 187.1-187.32; 205/334, 701, 755, 756.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 5,674,537 A (MORROW) 07 October 1997, column 3, line 28 to column 5, line 19, Example I at column 14, Example IV at column 15, claims 1-6.	1-7 --- 1-8
X -- Y	US 3,616,355 A (THEMY) 26 October 1971, column 2, lines 16-69, column 3, line 62 to column 4, line 22, column 5, line 15 to column 6, line 36, Example VIII at columns 8-9, claims 1-3.	1-2, 4-6 ----- 1-8
Y	Chem. abstr., Vol. 94, No. 7, 16 November 1981 (Columbus, OH, USA), page 102, column 2, the abstract No. 41943u, SKALIY, P. et al. 'Laboratory Studies of Disinfectants against Legionella pneumophila.' Appl. Environ. Microbiol. 1980, 40(4), 697-700.	1-8

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

19 DECEMBER 1998

Date of mailing of the international search report

21 JAN 1999

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JOHN PAK

Telephone No. 308-1235

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/22372

A. CLASSIFICATION OF SUBJECT MATTER:

IPC (6):

A61K 33/00, 33/04, 33/14, 33/20, 33/40; A01N 59/00, 59/02, 59/08; A61L 2/00, 2/02, 2/16, 2/18, 9/14; C01B 7/03, 11/00, 13/00, 15/00; C25B 1/00, 1/02, 1/04, 1/14, 1/24, 1/26, 1/28, 1/30, 1/34.

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

424/600, 613, 615, 616, 661-665, 677-681; 422/22, 23, 29, 37; 252/186.21, 186.22, 187.1-187.32; 205/334, 701, 755, 756.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: GARY M. NATH
NATH & ASSOCIATES
1030 15TH STREET, N.W.
6TH FLOOR
WASHINGTON, DC 20005-1503

RECEIVED
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NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

06 APR 2000

Applicant's or agent's file reference

23739-PCT

IMPORTANT NOTIFICATION

International application No.

PCT/US98/22372

International filing date (day/month/year)

23 OCTOBER 1998

Priority Date (day/month/year)

23 OCTOBER 1997

Applicant

MOISEL, EKKEHARD WALTER

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US
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PATENT COOPERATION TREATY

From the
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To: GARY M. NATH
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WASHINGTON, DC 20005-1503

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing (day/month/year) 06 APR 2000	
Applicant's or agent's file reference 23739-PCT	IMPORTANT NOTIFICATION
International application No. PCT/US98/22372	International filing date (day/month/year) 23 OCTOBER 1998
Priority Date (day/month/year) 23 OCTOBER 1997	
Applicant MOISEL, EKKEHARD WALTER	

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

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For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer JOHN PAE
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 23739-PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US98/22372	International filing date (day/month/year) 23 OCTOBER 1998	Priority date (day/month/year) 23 OCTOBER 1997
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant MOISEL, EKKEHARD WALTER		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>4</u> sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step or industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 21 MAY 1999	Date of completion of this report 28 FEBRUARY 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer JOHN PAK
Facsimile No. (703) 305-3230	Telephone No. 308-1235

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/22372

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments):*

- ☐ the international application as originally filed.
- ☒ the description, pages (See Attached) , as originally filed.
pages _____ , filed with the demand.
pages _____ , filed with the letter of _____
pages _____ , filed with the letter of _____
- ☒ the claims, Nos. (See Attached) , as originally filed.
Nos. _____ , as amended under Article 19.
Nos. _____ , filed with the demand.
Nos. _____ , filed with the letter of _____
Nos. _____ , filed with the letter of _____
- ☒ the drawings, sheets/fig (See Attached) , as originally filed.
sheets/fig _____ , filed with the demand.
sheets/fig _____ , filed with the letter of _____
sheets/fig _____ , filed with the letter of _____

2. The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 1

because:

☒ the said international application, or the said claim Nos. 1 relate to the following subject matter which does not require international preliminary examination (*specify*).

Claim 1 is directed to the "use of a composition." This IPEA is not required to examine such "use" type claims because the exact nature of the claimed invention is so unclear that a meaningful opinion cannot be formed on the novelty, inventive step or industrial applicability of the claimed invention. PCT Article 34(4)(a)(ii); see also PCT Rule 67.1.

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*).

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. .

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

THE INTERNATIONAL PATENT CLASSIFICATION (IPC) AND/OR THE NATIONAL CLASSIFICATION ARE AS LISTED BELOW:

IPC(8): A61K 33/00, 33/04, 33/14, 33/20, 33/40; A01N 59/00, 59/02, 59/08; A61L 2/00, 2/02, 2/16, 2/18, 9/14; C01B 7/03, 11/00, 13/00, 15/00; C25B 1/00, 1/02, 1/04, 1/14, 1/24, 1/26, 1/28, 1/30, 1/34, AND US CL.: 424/600, 613, 615, 616, 661-665, 677-681; 422/22, 23, 29, 37; 252/186.21, 186.22, 187.1-187.32; 205/334, 701, 755, 756.

I. BASIS OF REPORT:

THIS REPORT HAS BEEN DRAWN ON THE BASIS OF THE DESCRIPTION,
PAGES, 1-8, AS ORIGINALLY FILED.

PAGES, NONE, FILED WITH THE DEMAND.

AND ADDITIONAL AMENDMENTS:

NONE

THIS REPORT HAS BEEN DRAWN ON THE BASIS OF THE CLAIMS,
NUMBERS, NONE, AS ORIGINALLY FILED.

NUMBERS, NONE, AS AMENDED UNDER ARTICLE 19.

NUMBERS, NONE, FILED WITH THE DEMAND.

AND ADDITIONAL AMENDMENTS:

CLAIMS 1-8, FILED WITH THE LETTER OF 09 DECEMBER 1999.

THIS REPORT HAS BEEN DRAWN ON THE BASIS OF THE DRAWINGS,
SHEETS, NONE, AS ORIGINALLY FILED.

SHEETS, NONE, FILED WITH THE DEMAND.

AND ADDITIONAL AMENDMENTS:

SHEETS 1-2, FILED WITH THE LETTER OF 09 DECEMBER 1999.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (CONTINUED):

MICROORGANISMS (PAGE 190). CHLORINE COMPOUNDS SUCH AS HYPOCHLORITE ARE KNOWN TO BE USED AS DISINFECTANTS, PARTICULARLY FOR DISINFECTING WATER SUPPLIES (PAGE 1530).

VETU ABSTRACTS 1985-63045 DISCLOSES THE USE OF SODIUM HYPOCHLORITE TO DISINFECT SWINE PENS TO PREVENT DISEASES. VETU ABSTRACT 1988-60359 TEACHES THE IMPORTANCE OF DISINFECTANTS IN PREVENTING COCCIDIOSIS IN NEONATAL PIGS. VETU ABSTRACT 1994-62049 DISCLOSES THE BENEFIT OF WATER DISINFECTION AS PART OF A THERAPY REGIMEN TO CONTROL INFECTIONS OF E. COLI, NEWCASTLE DISEASE AND INFECTIOUS BURSAL DISEASE IN BROILER FLOCKS.

KROSCHWITZ ET AL. (KIRK-OTHMER ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY) ARE CITED TO ESTABLISH THAT THE ELECTROCHEMICAL REACTOR FEATURES OF THE INSTANT INVENTION IS CONVENTIONAL ELECTROLYSIS TECHNOLOGY THAT WOULD HAVE BEEN WITHIN THE SKILL OF THE ROUTINEER IN THE ART (SEE PAGES 124-133, 135-140). VARIOUS OXYCHLORINE SPECIES ARE DISCLOSED UPON ELECTROLYSIS OF A CHLORIDE SOLUTION (PAGES 133-135).

THE CITED REFERENCES ESTABLISH THAT ELECTROLYZED AQUEOUS SOLUTIONS OF SODIUM CHLORIDE IS AN OLD AND KNOWN SUBSTANCE THAT HAS MICROBICIDAL ACTIVITY FOR IN VITRO OR IN VIVO USES. THE REFERENCES ALSO ESTABLISH THAT PATHOGENIC MICROORGANISMS INFECT LIVE ANIMALS AND THAT USE OF DISINFECTANTS TO DISINFECT AND/OR TREAT WATER SUPPLIES IS A BENEFICIAL TO CONTROLLING INFECTIONS. THEREFORE, THE ROUTINEER IN THE ART WOULD HAVE BEEN MOTIVATED TO ADMINISTER ELECTROCHEMICALLY "ACTIVATED" SOLUTION OF ANION CONTAINING SOLUTIONS SUCH AS AQUEOUS SODIUM CHLORIDE SOLUTIONS TO LIVE ANIMALS TO CONTROL PATHOGENIC INFECTIONS. MOTIVATION TO ATOMIZE THE ELECTROLYZED SOLUTION ARISES FROM THE KNOWN BENEFITS OF SPRAYING ATOMIZED SOLUTIONS OF HYPOCHLORITE (A MAJOR COMPONENT OF ELECTROLYZED SOLUTION) ON HUMAN BEINGS AND VARIOUS SUBSTRATES, THE EASE OF RAPID ADMINISTRATION TO LARGE NUMBER OF LIVE ANIMALS WHILE ALSO ACHIEVING DISINFECTION OF THE TREATED AREA.

APPLICANT'S REMARKS FILED IN THE LETTER OF 09 DECEMBER 1999 HAVE BEEN GIVEN DUE CONSIDERATION BUT WERE FOUND UNPERSUASIVE. APPLICANT ARGUES THAT THE PRIOR ART ELECTROCHEMICALLY ACTIVATED ANION-CONTAINING AQUEOUS SOLUTION CONTAINS HYPOCHLORITE AND HYPOCHLOROUS ACID, WHICH ARE ALLEGEDLY "POISONOUS," AND THEREFORE, IT WOULD BE UNSAFE TO ATOMIZE AND ADMINISTER SUCH SUBSTANCES TO ANIMALS. APPLICANT'S ARGUMENT IS UNPERSUASIVE BECAUSE (i) HIS OWN INVENTION CONTAINS SUCH ALLEGEDLY "POISONOUS" SUBSTANCES (SEE CLAIM 5), AND (ii) ATOMIZED DILUTE SOLUTIONS OF HYPOCHLORITE HAS BEEN TAUGHT TO SAFELY TREAT HUMAN BEINGS - SEE BR 9201704. AS VARIOUS OXYCHLORINE SPECIES ARE IN EQUILIBRIUM WITH ONE ANOTHER IN SOLUTION, THE ROUTINEER IN THE ART WOULD HAVE EXPECTED SIMILARLY CONCENTRATED

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>2-8</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>2-8</u>	NO
Industrial Applicability (IA)	Claims <u>2-8</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claim 2-8 meets the criteria set forth in PCT Article 33(2), because no single prior art reference can be found that explicitly discloses a composition and method of treating live animals for pathogenic microorganism infections with said composition wherein the composition comprises an atomized electrochemically activated anion-containing aqueous solution.

Claims 2-8 meet the criteria set forth in PCT Article 33(4), because the claimed invention finds industrial applicability in the treatment of live animals against pathogenic microorganisms.

Claims 2-8 lack an inventive step under PCT Article 33(3) as being obvious over the combined teachings of Morrow and Themy in view of Imai (BR 9201704), Fraser et al. (The Merck Veterinary Manual), VETU Abstracts 1985-63045, 1988-60359 and 1994-62049 and Kroschwitz et al. (Kirk-Othmer Encyclopedia of Chemical Technology).

Morrow explicitly discloses the use of electrolyzed sodium chloride to treat the host animal for variety of pathogenic diseases (see from column 3, line 28 to column 5, line 19; Examples I, IV, X-XII, XVI, XVII; claims 1-6). Electrolysis reaction produces ozone and various oxychlorine species such as hypochlorous acid and hypochlorite (see from column 4, line 46 to column 5, line 19). Morrow also discloses the well-known fact that products resulting from electrolysis of saline solutions have long been known as in vitro microbicides, and have been used to keep water free of pathogenic organisms such as *E. coli* (see from column 5, line 56 to column 6, line 9).

Themy explicitly discloses electrolyzed sodium chloride solutions (column 2, lines 9-47; Examples I, II, IX; claims 1-13). Electrolysis reaction produces ozone and various oxychlorine species such as hypochlorite (column 2, lines 24-40).

Imai (BR 9201704) discloses 10-100 ppm solutions of hypochlorite that have particle size range of 70-150 microns, which are sprayed to open areas, foodstuffs, *as well as to people* without damage to materials or eyes, for the control of cholera epidemics. See the entire disclosure and claims 1-6, and also an English abstract thereof, Derwent Abstract, No. 1994-035498.

Fraser et al. (The Merck Veterinary Manual) discloses that intestinal diseases in pigs can be caused by variety of
(Continued on Supplemental Sheet.)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/22372

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 11

SOLUTIONS OF HYPOCHLORITE OR OTHER OXYCHLORINE SPECIES TO BE SIMILARLY SAFE FOR ATOMIZATION AND ADMINISTRATION TO ANIMALS.

FOR THESE REASONS, THE CLAIMED INVENTION AS A WHOLE IS DEEMED OBVIOUS AS BEING FAIRLY SUGGESTED BY THE COMBINED TEACHINGS OF THE PRIOR ART, AND THE CLAIMS ARE THEREFORE DEEMED TO LACK AN INVENTIVE STEP UNDER PCT ARTICLE 33(3).

NEW CITATIONS

KROSCWITZ, JACQUELINE I. ET AL. (EDS.). KIRK-OTHMER ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY. NEW YORK: JOHN WILEY & SONS. 1994, VOL. 9, PAGES 124-140, ESPECIALLY PAGES 124 AND 133-135.

FRASER, CLARENCE M. ET AL. (EDS.) THE MERCK VETERINARY MANUAL. NEW JERSEY: MERCK & CO., INC. 1991, PAGES 190, 1529-1531.

DATABASE VETU ON STN, DERWENT VETERINARY DRUG FILE, LONDON: DERWENT PUBLICATIONS LTD., AN 1994-62049, MUKHERJEE, W.R. ET AL. 'OCCURRENCE OF ESCHERICHIA COLI, NEWCASTLE DISEASE VIRUS AND INFECTIOUS BURSAL DISEASE VIRUS IN BROILERS,' ABSTRACT, INDIAN VET. J., 1994.

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BR 920 1704 A (IMAI) 03 NOVEMBER 1993, SEE THE ENTIRE DISCLOSURE AND CLAIMS 1-6.

DATABASE DERWENT ON WEST, DERWENT INFORMATION LTD., (LONDON, GB), NO. 1994-035498, BR 920 1704 A (IMAI) 03 NOVEMBER 1993.

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413

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 33/00, 33/04, 33/14, 33/20, 33/40, A01N 59/00, 59/02, 59/08, A61L 2/00, 2/02, 2/16, 2/18, 9/14, C01B 7/03, 11/00, 13/00, 15/00, C25B 1/00, 1/02, 1/04, 1/14, 1/24, 1/26, 1/28, 1/30, 1/34	A1	(11) International Publication Number: WO 99/20287 (43) International Publication Date: 29 April 1999 (29.04.99)
(21) International Application Number: PCT/US98/22372 (22) International Filing Date: 23 October 1998 (23.10.98) (30) Priority Data: 97/9486 23 October 1997 (23.10.97) ZA (71) Applicant (for all designated States except US): MOISEL, Ekkehard, Walter [ZA/ZA]; 22 Forge Road, Spartan 1619 (ZA). (71) Applicant (for BB only): DAVIS, Joanne, T. [US/US]; 714A 15th Street, Arlington, VA 22202 (US). (71)(72) Applicant and Inventor: HINZE, Gilbert, Theo [ZA/ZA]; 119 Ostrich Road, Bromhof, Randburg 2194 (ZA). (74) Agent: NATH, Gary, M.; Nath & Associates, 6th floor, 1030 15th Street, N.W., Washington, DC 20005 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published With international search report.
(54) Title: THE USE OF AN AQUEOUS SOLUTION IN THE PREPARATION OF A MEDICAMENT FOR USE IN THE TREATMENT OF LIVE ANIMALS		
(57) Abstract This invention relates to a composition for use in the treatment of pathogenic microorganisms in a live animal, the composition comprising an electro-chemically activated, anion-containing aqueous solution.		

FOR THE PURPOSES OF INFORMATION ONLY

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THE USE OF AN AQUEOUS SOLUTION IN THE PREPARATION
OF A MEDICAMENT FOR USE IN THE TREATMENT OF LIVE
ANIMALS

Field of the Invention :

This invention relates to the use of an aqueous solution in the preparation of a medicament for use in the treatment of live animals.

Background to the Invention :

For the purposes of this specification, the term "animal" should be construed to include within its meaning sheep, cattle, goats, pigs, chickens, ostriches, reptiles and the like; the term "disease" should be construed to include within its meaning diarrhoea; the term pathogen should be construed to include within its meaning micro-organisms such as E-coli; and the term "medicament" should be construed to include within its meaning oral bactericides and bactericidal inhalants. The Applicant envisages that the invention will be applicable particularly, but not exclusively, in the preparation of a medicament for use in the treatment of pathogenic micro-organisms in weaner piglets and chicklets.

The presence of antibiotic residues in food products lead to allergic and anaphylactic reactions in humans. The development of resistant strains of micro-organisms makes anti-microbials ineffective.

Object of the Invention :

It is accordingly an object of the invention to provide inexpensive, novel and alternative anti-microbials that overcome the above disadvantages.

In accordance with a first aspect of the invention, there is provided the use of a composition in the preparation of a medicament for use in the treatment of pathogenic micro-organisms in a live animal, the composition comprising an electro-chemically activated anion-containing aqueous solution.

5 In accordance with a second aspect of the invention there is provided a composition in the preparation of a medicament for the treatment of pathogenic micro-organisms in live animals, the composition comprising an electro-chemically activated anion-containing aqueous solution, the composition substantially as herein defined.

10 In accordance with a third aspect of the invention there is provided a method of treating pathogenic micro-organisms in a live animal, the method including the step of administering a dosage of a composition comprising an electro-chemically activated anion-containing aqueous solution to the animal, the anion-containing aqueous solution being substantially as herein defined.

15 The anion-containing aqueous solution may be prepared by means of electrolysis of an aqueous solution of a salt. The salt may be sodium chloride. In particular, it may be non-iodated sodium chloride or potassium chloride.

The anion-containing solution and the associated cation-containing solution may be produced by an electro-chemical reactor or so-called electrolysis device.

5 The electro-chemical reactor may include a through flow, electro-chemical cell having two co-axial cylindrical electrodes with a co-axial diaphragm between the electrodes so as to separate an annular inter electrode space into a catalytic and an analytic chamber.

The anion-containing solution is referred to hereinafter for brevity as the "anolyte solution" and the cation-containing solution is referred to hereinafter
10 for brevity as the "catholyte solution".

The anolyte solution may be produced from an aqueous NaCl solution, electrolysed to produce radical cation and radical anion species, the anolyte solution having a redox potential up to about + 600 mV to + 800 mV. These species may be labile and after about 96 hours, the various radical species may
15 disappear with no residues being produced.

The anolyte solution may have a pH of about 6,5 to 7,5. The anolyte solution may include species such as ClO ; ClO^\cdot ; HClO ; OH^\cdot ; HO_2^\cdot ; H_2O_2 ; O_3 ; $\text{S}_2\text{O}_8^{2-}$ and $\text{Cl}_2\text{O}_6^{2-}$.

These species have been found to have a synergistic anti-bacterial and/or anti-viral effect which is generally stronger than that of chemical bactericides and has been found to be particularly effective against viral organisms and spore and cyst forming bacteria.

- 5 The redox potential of the anolyte solution may be monitored during the process so that the treatment process may be monitored and controlled on a continuous basis.

The catholyte solution generally may have a pH of up to about 12-13 and a redox potential of about -980 mV. The catholyte solution may include species
10 such as NaOH; KOH; $\text{Ca}(\text{OH})_2$; $\text{Mg}(\text{OH})_2$; HO^\cdot ; $\text{H}_3\text{O}_2^\cdot$; HO_2^\cdot ; H_2O_2 ; O_2^\cdot ; OH^- ; O_2^{2-} .

The method of treatment may include administering the anolyte solution by soaking, rinsing or dipping the animal in the anolyte solution, applying the anolyte solution as an inhalant via an atomising or fogging process or
15 administering the anolyte solution orally. The soaking, rinsing or dipping process is suitable for animals which can be handled with relative ease.

The processes of atomising or fogging and oral administration by addition to drinking water are both suitable for animals such as weaner piglets and

chicklets which are susceptible to stress and accompanying weight loss. The atomising or fogging process may include the step of atomising the solution into the atmosphere in a volume to be treated, forming droplets of between 5 and 100 micrometre. The method may include the preliminary step of enclosing the volume to be treated prior to atomising or fogging the enclosed volume.

The atomising or fogging process is preferably conducted at pre-determined intervals so as to maintain a suitable level of anolyte concentration in the atmosphere, thus utilising the optimum microcidal and other properties of the anolyte solution in accordance with the required administration rate.

The anolyte solution may also be applied by an atomising process in air ducting systems to destroy air-borne micro-organisms and to destroy micro-organisms present in the airways and lung tissue by inhalation.

The treatment of the animal as described above may be conducted so as to improve the weight gain as a result of the anti-microbial action of the anolyte solution.

The oxidising-free radicals present in the anolyte solution may act synergistically at a bacterial cellular level.

The anolyte solution may have a specific anion concentration and distribution and a redox potential in accordance with the specific application.

The pathogenic micro-organisms to be treated may include enteric pathogenic micro-organisms and respiratory pathogenic micro-organisms.

5 Detailed Description of the Invention :

A preferred embodiment of the invention will now be described with reference to the accompanying experiments.

In a series of experiments, the bactericidal effect of the anolyte solution was tested on animals. The results are reflected in the tables below.

10 An electro-chemical reactor, including a through flow, electro-chemical cell having two co-axial cylindrical electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into a catalytic and an analytic chamber, was used to produce anolyte and catholyte solutions.

Experiment 1 - Weaner Piglets

15 The anolyte solution was added to the drinking water of the weaner piglets over a period of 14 days and the results were measured in terms of average

weight after the 14 day period. The average weight of the administered groups were compared with the average weight of the unadministered groups.

The administered groups showed relative weight gain relative to the unadministered groups. The relative weight gains of the administered groups
5 are reflected in Table 1 below.

Experiment 2 - Broilers (Chicklets)

Day old broilers were administered with anolyte solution (10% diluted) by addition to drinking water for 7 days. (Group C3 - 12 000 chicklets). No antibiotic medication was administered during that time. Untreated control
10 groups (C1, C2, C4 and C5 = total 48 000 chicklets) received normal drinking water during that time. The untreated groups were routinely medicated with Tylosin for 3 consecutive days.

Bacterial analyses of the drinking water of all groups were regularly conducted during the first 7 days. Other measurements included daily mortalities and
15 morbidities throughout and pH and ORP determinations of the drinking water during the first 7 days. All results are reflected in Table 2 below.

Medication of drinking water with anolyte solution supplied to day-old

chicklets for the first period resulted in a significant reduction in mortalities throughout the growth and finishing period. Mortalities increased in all the groups from the 4th week onwards mainly due to respiratory disease. It is envisaged that these could be reduced by fogging the environment with anolyte solution to eliminate airborne respiratory pathogens by means of respiratory intake.

It has been found that the efficacy of the use of the anolyte solution in the treatment of live animals depends upon the concentration of the anions in the anolyte solution, as measured by the oxidation-reduction potential (ORP) or redox potential of the anolyte solution, the flow rate through the reactor, the exposure time, i.e. the contact time between the contaminated animal and the anolyte solution and the temperature during application. By measuring the redox potential of the anolyte solution during the treatment, for example, of a weaner piglet, the available free radical concentration can be monitored. Anolyte solution has been found to be more effective at lower than at higher temperatures.

It will be appreciated that many variations in detail are possible without departing from the scope and/or spirit of the invention as claimed in the claims hereinafter.

1. The use of a composition in the preparation of a medicament for use in the treatment of pathogenic micro-organisms in a live animal, the composition comprising an electro-chemically activated, anion-containing aqueous solution.
2. A composition for the preparation of a medicament for the treatment of pathogenic micro-organisms in live animals, the composition comprising an electro-chemically activated anion-containing aqueous solution.
3. A method of treating pathogenic micro-organisms in a live animal, the method including the step of administering a dosage of a composition comprising an electro-chemically activated anion-containing aqueous solution to the animal
4. A composition as claimed in claim 2 wherein the anion-containing aqueous solution is prepared by means of electrolysis of an aqueous solution of a salt.
5. A composition as claimed in claim 2 wherein the anion-containing solution is produced by an electro-chemical reactor, the electro-chemical

reactor including a through flow, electro-chemical cell having two co-axial cylindrical electrodes with a co-axial diaphragm between the electrodes so as to separate an annular inter electrode space into a catalytic and an analytic chamber.

6. A composition as claimed in claim 2 wherein the anion containing aqueous solution has a redox potential up to about +600 mV and 800 mV and a pH of about 6,5 to 7,5.
7. A method of treatment as claimed in claim 3 including at least one of the steps of administering the solution by soaking, rinsing or dipping the animal in the solution, applying the solution as an inhalant via an atomising or fogging process, and administering the solution orally.
8. A method as claimed in claim 7 wherein the atomising or fogging process includes the step of atomising the solution into the atmosphere in a volume to be treated, forming droplets of between 5 and 100 micrometre..

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/22372

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : Please See Extra Sheet.

US CL : Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/600, 613, 615, 616, 661-665, 677-681; 422/22, 23, 29, 37; 252/186.21, 186.22, 187.1-187.32; 205/334, 701, 755, 756.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 5,674,537 A (MORROW) 07 October 1997, column 3, line 28 to column 5, line 19, Example I at column 14, Example IV at column 15, claims 1-6.	1-7 ---- 1-8
X -- Y	US 3,616,355 A (THEMY) 26 October 1971, column 2, lines 16-69, column 3, line 62 to column 4, line 22, column 5, line 15 to column 6, line 36, Example VIII at columns 8-9, claims 1-3.	1-2, 4-6 ----- 1-8
Y	Chem. abstr., Vol. 94, No. 7, 16 November 1981 (Columbus, OH, USA), page 102, column 2, the abstract No. 41943u, SKALIY, P. et al. 'Laboratory Studies of Disinfectants against Legionella pneumophila.' Appl. Environ. Microbiol. 1980, 40(4), 697-700.	1-8

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

19 DECEMBER 1998

Date of mailing of the international search report

21 JAN 1999

Name and mailing address of the ISA/US
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Authorized officer

JOHN PAK

Telephone No. 308-1235

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/22372

A. CLASSIFICATION OF SUBJECT MATTER:

IPC (6):

A61K 33/00, 33/04, 33/14, 33/20, 33/40; A01N 59/00, 59/02, 59/08; A61L 2/00, 2/02, 2/16, 2/18, 9/14; C01B 7/03, 11/00, 13/00, 15/00; C25B 1/00, 1/02, 1/04, 1/14, 1/24, 1/26, 1/28, 1/30, 1/34.

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

424/600, 613, 615, 616, 661-665, 677-681; 422/22, 23, 29, 37; 252/186.21, 186.22, 187.1-187.32; 205/334, 701, 755, 756.

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16 C3

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

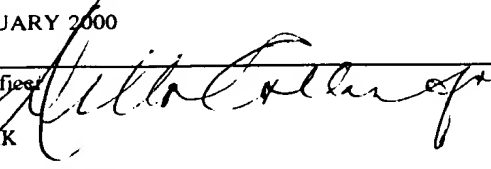
Applicant's or agent's file reference 23739-PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US98/22372	International filing date (day/month/year) 23 OCTOBER 1998	Priority date (day/month/year) 23 OCTOBER 1997
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant MOISEL, ERKHARD WALTER] RADICAL WATERS IP (PTY) LTD		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets.
- ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

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Date of submission of the demand 21 MAY 1999	Date of completion of this report 28 FEBRUARY 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  JOHN PAK
Facsimile No. (703) 305-3230	Telephone No. 308-1235

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/22372

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments):*

☐ the international application as originally filed.

☒ the description, pages (See Attached), as originally filed.

pages _____, filed with the demand.

pages _____, filed with the letter of _____.

pages _____, filed with the letter of _____.

☒ the claims, Nos. (See Attached), as originally filed.

Nos. _____, as amended under Article 19.

Nos. _____, filed with the demand.

Nos. _____, filed with the letter of _____.

Nos. _____, filed with the letter of _____.

☒ the drawings, sheets/fig (See Attached), as originally filed.

sheets/fig _____, filed with the demand.

sheets/fig _____, filed with the letter of _____.

sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE.

☒ the claims, Nos. NONE.

☒ the drawings, sheets/fig NONE.

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US98/22372**III. N n-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 1

because:

☒ the said international application, or the said claim Nos. 1 relate to the following subject matter which does not require international preliminary examination (*specify*).

Claim 1 is directed to the "use of a composition." This IPEA is not required to examine such "use" type claims because the exact nature of the claimed invention is so unclear that a meaningful opinion cannot be formed on the novelty, inventive step or industrial applicability of the claimed invention. PCT Article 34(4)(a)(ii); see also PCT Rule 67.1.

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*).

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>2-8</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>2-8</u>	NO
Industrial Applicability (IA)	Claims <u>2-8</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claim 2-8 meets the criteria set forth in PCT Article 33(2), because no single prior art reference can be found that explicitly discloses a composition and method of treating live animals for pathogenic microorganism infections with said composition wherein the composition comprises an atomized electrochemically activated anion-containing aqueous solution.

Claims 2-8 meet the criteria set forth in PCT Article 33(4), because the claimed invention finds industrial applicability in the treatment of live animals against pathogenic microorganisms.

Claims 2-8 lack an inventive step under PCT Article 33(3) as being obvious over the combined teachings of Morrow and Themy in view of Imai (BR 9201704), Fraser et al. (The Merck Veterinary Manual), VETU Abstracts 1985-63045, 1988-60359 and 1994-62049 and Kroschwitz et al. (Kirk-Othmer Encyclopedia of Chemical Technology).

Morrow explicitly discloses the use of electrolyzed sodium chloride to treat the host animal for variety of pathogenic diseases (see from column 3, line 28 to column 5, line 19; Examples I, IV, X-XII, XVI, XVII; claims 1-6). Electrolysis reaction produces ozone and various oxychlorine species such as hypochlorous acid and hypochlorite (see from column 4, line 46 to column 5, line 19). Morrow also discloses the well-known fact that products resulting from electrolysis of saline solutions have long been known as in vitro microbicides, and have been used to keep water free of pathogenic organisms such as E. coli (see from column 5, line 56 to column 6, line 9).

Themy explicitly discloses electrolyzed sodium chloride solutions (column 2, lines 9-47; Examples I, II, IX; claims 1-13). Electrolysis reaction produces ozone and various oxychlorine species such as hypochlorite (column 2, lines 24-40).

Imai (BR 9201704) discloses 10-100 ppm solutions of hypochlorite that have particle size range of 70-150 microns, which are sprayed to open areas, foodstuffs, *as well as to people* without damage to materials or eyes, for the control of cholera epidemics. See the entire disclosure and claims 1-6, and also an English abstract thereof, Derwent Abstract, No. 1994-035498.

Fraser et al. (The Merck Veterinary Manual) discloses that intestinal diseases in pigs can be caused by variety of (Continued on Supplemental Sheet.)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/22372

Supplemental B x

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

THE INTERNATIONAL PATENT CLASSIFICATION (IPC) AND/OR THE NATIONAL CLASSIFICATION ARE AS LISTED BELOW:

IPC(6): A61K 33/00, 33/04, 33/14, 33/20, 33/40; A01N 59/00, 59/02, 59/08; A61L 2/00, 2/02, 2/16, 2/18, 9/14; C01B 7/03, 11/00, 13/00, 15/00; C25B 1/00, 1/02, 1/04, 1/14, 1/24, 1/26, 1/28, 1/30, 1/34, AND US CL.: 424/600, 613, 615, 616, 661-665, 677-681; 422/22, 23, 29, 37; 252/186.21, 186.22, 187.1-187.32; 205/334, 701, 755, 756.

I. BASIS OF REPORT:

THIS REPORT HAS BEEN DRAWN ON THE BASIS OF THE DESCRIPTION,
PAGES, 1-8, AS ORIGINALLY FILED.

PAGES, NONE, FILED WITH THE DEMAND.

AND ADDITIONAL AMENDMENTS:

NONE

THIS REPORT HAS BEEN DRAWN ON THE BASIS OF THE CLAIMS,

NUMBERS, NONE, AS ORIGINALLY FILED.

NUMBERS, NONE, AS AMENDED UNDER ARTICLE 19.

NUMBERS, NONE, FILED WITH THE DEMAND.

AND ADDITIONAL AMENDMENTS:

CLAIMS 1-8, FILED WITH THE LETTER OF 09 DECEMBER 1999.

THIS REPORT HAS BEEN DRAWN ON THE BASIS OF THE DRAWINGS,

SHEETS, NONE, AS ORIGINALLY FILED.

SHEETS, NONE, FILED WITH THE DEMAND.

AND ADDITIONAL AMENDMENTS:

SHEETS 1-2, FILED WITH THE LETTER OF 09 DECEMBER 1999.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (CONTINUED):

MICROORGANISMS (PAGE 190). CHLORINE COMPOUNDS SUCH AS HYPOCHLORITE ARE KNOWN TO BE USED AS DISINFECTANTS, PARTICULARLY FOR DISINFECTING WATER SUPPLIES (PAGE 1530).

VETU ABSTRACTS 1985-63045 DISCLOSES THE USE OF SODIUM HYPOCHLORITE TO DISINFECT SWINE PENS TO PREVENT DISEASES. VETU ABSTRACT 1988-60359 TEACHES THE IMPORTANCE OF DISINFECTANTS IN PREVENTING COCCIDIOSIS IN NEONATAL PIGS. VETU ABSTRACT 1994-62049 DISCLOSES THE BENEFIT OF WATER DISINFECTION AS PART OF A THERAPY REGIMEN TO CONTROL INFECTIONS OF E. COLI, NEWCASTLE DISEASE AND INFECTIOUS BURSAL DISEASE IN BROILER FLOCKS.

KROSCWITZ ET AL. (KIRK-OTTMER ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY) ARE CITED TO ESTABLISH THAT THE ELECTROCHEMICAL REACTOR FEATURES OF THE INSTANT INVENTION IS CONVENTIONAL ELECTROLYSIS TECHNOLOGY THAT WOULD HAVE BEEN WITHIN THE SKILL OF THE ROUTINEER IN THE ART (SEE PAGES 124-133, 135-140). VARIOUS OXYCHLORINE SPECIES ARE DISCLOSED UPON ELECTROLYSIS OF A CHLORIDE SOLUTION (PAGES 133-135).

THE CITED REFERENCES ESTABLISH THAT ELECTROLYZED AQUEOUS SOLUTIONS OF SODIUM CHLORIDE IS AN OLD AND KNOWN SUBSTANCE THAT HAS MICROBICIDAL ACTIVITY FOR IN VITRO OR IN VIVO USES. THE REFERENCES ALSO ESTABLISH THAT PATHOGENIC MICROORGANISMS INFECT LIVE ANIMALS AND THAT USE OF DISINFECTANTS TO DISINFECT AND/OR TREAT WATER SUPPLIES IS A BENEFICIAL TO CONTROLLING INFECTIONS. THEREFORE, THE ROUTINEER IN THE ART WOULD HAVE BEEN MOTIVATED TO ADMINISTER ELECTROCHEMICALLY "ACTIVATED" SOLUTION OF ANION CONTAINING SOLUTIONS SUCH AS AQUEOUS SODIUM CHLORIDE SOLUTIONS TO LIVE ANIMALS TO CONTROL PATHOGENIC INFECTIONS. MOTIVATION TO ATOMIZE THE ELECTROLYZED SOLUTION ARISES FROM THE KNOWN BENEFITS OF SPRAYING ATOMIZED SOLUTIONS OF HYPOCHLORITE (A MAJOR COMPONENT OF ELECTROLYZED SOLUTION) ON HUMAN BEINGS AND VARIOUS SUBSTRATES, THE EASE OF RAPID ADMINISTRATION TO LARGE NUMBER OF LIVE ANIMALS WHILE ALSO ACHIEVING DISINFECTION OF THE TREATED AREA.

APPLICANT'S REMARKS FILED IN THE LETTER OF 09 DECEMBER 1999 HAVE BEEN GIVEN DUE CONSIDERATION BUT WERE FOUND UNPERSUASIVE. APPLICANT ARGUES THAT THE PRIOR ART ELECTROCHEMICALLY ACTIVATED ANION-CONTAINING AQUEOUS SOLUTION CONTAINS HYPOCHLORITE AND HYPOCHLOROUS ACID, WHICH ARE ALLEGEDLY "POISONOUS," AND THEREFORE, IT WOULD BE UNSAFE TO ATOMIZE AND ADMINISTER SUCH SUBSTANCES TO ANIMALS. APPLICANT'S ARGUMENT IS UNPERSUASIVE BECAUSE (i) HIS OWN INVENTION CONTAINS SUCH ALLEGEDLY "POISONOUS" SUBSTANCES (SEE CLAIM 5), AND (ii) ATOMIZED DILUTE SOLUTIONS OF HYPOCHLORITE HAS BEEN TAUGHT TO SAFELY TREAT HUMAN BEINGS - SEE BR 9201704. AS VARIOUS OXYCHLORINE SPECIES ARE IN EQUILIBRIUM WITH ONE ANOTHER IN SOLUTION, THE ROUTINEER IN THE ART WOULD HAVE EXPECTED SIMILARLY CONCENTRATED

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 11

SOLUTIONS OF HYPOCHLORITE OR OTHER OXYCHLORINE SPECIES TO BE SIMILARLY SAFE FOR ATOMIZATION AND ADMINISTRATION TO ANIMALS.

FOR THESE REASONS, THE CLAIMED INVENTION AS A WHOLE IS DEEMED OBVIOUS AS BEING FAIRLY SUGGESTED BY THE COMBINED TEACHINGS OF THE PRIOR ART, AND THE CLAIMS ARE THEREFORE DEEMED TO LACK AN INVENTIVE STEP UNDER PCT ARTICLE 33(3).

----- NEW CITATIONS -----

KROSCWITZ, JACQUELINE I. ET AL. (EDS.). KIRK-OTHMER ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY. NEW YORK: JOHN WILEY & SONS. 1994, VOL. 9, PAGES 124-140, ESPECIALLY PAGES 124 AND 133-135.

FRASER, CLARENCE M. ET AL. (EDS.) THE MERCK VETERINARY MANUAL. NEW JERSEY: MERCK & CO., INC. 1991, PAGES 190, 1529-1531.

DATABASE VETU ON STN, DERWENT VETERINARY DRUG FILE, LONDON: DERWENT PUBLICATIONS LTD., AN 1994-62049, MUKHERJEE, W.R. ET AL. 'OCCURRENCE OF ESCHERICHIA COLI, NEWCASTLE DISEASE VIRUS AND INFECTIOUS BURSAL DISEASE VIRUS IN BROILERS,' ABSTRACT, INDIAN VET. J., 1994.

DATABASE VETU ON STN, DERWENT VETERINARY DRUG FILE, LONDON: DERWENT PUBLICATIONS LTD., AN 1988-60359, TUBBS, R.C. 'CONTROLLING COCCIDIOSIS IN NEONATAL PIGS,' ABSTRACT, VET. MED., 1987.

DATABASE VETU ON STN, DERWENT VETERINARY DRUG FILE, LONDON: DERWENT PUBLICATIONS LTD., AN 1985-63045, STRAW, B.E. ET AL. 'INTERACTIONS OF MANAGEMENT AND ANIMAL PERFORMANCE IN A SWINE FEED,' ABSTRACT, J. AM. VET. MED. ASSOC., 1985.

BR 9201704 A (IMAI) 03 NOVEMBER 1993, SEE THE ENTIRE DISCLOSURE AND CLAIMS 1-6.

DATABASE DERWENT ON WEST, DERWENT INFORMATION LTD., (LONDON, GB), NO. 1994-035498, BR 9201704 A (IMAI) 03 NOVEMBER 1993.

PCT/US 98/22372

IPEA/US 09 DEC 1999

Claims:

1. The use of a composition in the preparation of a medicament for use in the treatment of pathogenic micro-organisms in a live animal, the composition comprising an atomized electro-chemically activated, anion-containing aqueous solution.
2. A composition for the preparation of a medicament for the treatment of pathogenic micro-organisms in live animals, the composition comprising an atomized electro-chemically activated anion-containing aqueous solution.
3. A method of treating pathogenic micro-organisms in a live animal, the method comprising the step of fogging the animal with a dosage of a composition comprising an atomized electro-chemically activated anion-containing solution.
4. A composition as claimed in claim 2 wherein the anion-containing aqueous solution is prepared by means of electrolysis of an aqueous solution of a salt.
5. A composition as claimed in claim 4 wherein the anion-containing solution includes species selected from the group comprising: ClO ; ClO^- ; HClO ; OH^- ; HO_2^- ; H_2O_2 ; O_3 ; $\text{S}_2\text{O}_8^{2-}$; and $\text{Cl}_2\text{O}_6^{2-}$.

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AMENDED SHEET

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6. A composition as claimed in claim 2 wherein the anion-containing solution is produced by an electro-chemical reactor, the electro-chemical reactor comprising a through flow, electro-chemical cell having two co-axial cylindrical electrodes with a co-axial diaphragm between the electrodes so as to separate an annular inter electrode space into a catalytic and an analytic chamber.

7. A composition as claimed in claim 2 wherein the anolyte solution has a redox potential of between +600mV and +800mV and a pH of between 6.5 and 7.5.

8. A method as claimed in claim 3 wherein the fogging process comprises the step of atomizing the solution into the atmosphere in a volume to be treated, forming droplets of between 5 and 100 micrometers.

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AMENDED SHEET

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TABLE 1

	Determinant	Trial Groups			
		R1IM	R2TF	R3CF	R4CM
Treatments	10% Anolyte in drinking water - days	13	13	0	0
	ORP range (mV)	600-650	600-650	100-150	100-150
	Replenishment (days)	2	2	-	-
Growth Performance	No per group	16	16	16	16
	(9/10/97) Day 0 x L Mass	8,24	6,08	7,66	6,01
	ADG	0,133	0,212	0,185	0,148
Treatment Courses Required	Diarrhea pig/group	(18%)	(12,5%)	(37,5%)	(100%)
	Respiratory symptoms pigs/group	(6,25%)	(12,5%)	(18,75%)	(100%)
	Cost of Treatment	R14,00	R14,00	R31,50	R126,00
	Cost of Treatment	R0,88	R0,88	R1,97	R7,41

AMENDED SHEET

Encl.
3

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GROUP 1600

1. The use of a composition in the preparation of a medicament for use in the treatment of pathogenic micro-organisms in a live animal, the composition comprising an electro-chemically activated, anion-containing aqueous solution.
2. A composition for the preparation of a medicament for the treatment of pathogenic micro-organisms in live animals, the composition comprising an electro-chemically activated anion-containing aqueous solution.
3. A method of treating pathogenic micro-organisms in a live animal, the method including the step of administering a dosage of a composition comprising an electro-chemically activated anion-containing aqueous solution to the animal
4. A composition as claimed in claim 2 wherein the anion-containing aqueous solution is prepared by means of electrolysis of an aqueous solution of a salt.
5. A composition as claimed in claim 2 wherein the anion-containing solution is produced by an electro-chemical reactor, the electro-chemical

reactor including a through flow, electro-chemical cell having two co-axial cylindrical electrodes with a co-axial diaphragm between the electrodes so as to separate an annular inter electrode space into a catalytic and an analytic chamber.

6. A composition as claimed in claim 2 wherein the anion containing aqueous solution has a redox potential up to about +600 mV and 800 mV and a pH of about 6,5 to 7,5.
7. A method of treatment as claimed in claim 3 including at least one of the steps of administering the solution by soaking, rinsing or dipping the animal in the solution, applying the solution as an inhalant via an atomising or fogging process, and administering the solution orally.
8. A method as claimed in claim 7 wherein the atomising or fogging process includes the step of atomising the solution into the atmosphere in a volume to be treated, forming droplets of between 5 and 100 micrometre..